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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,048	07/30/2001	Timothy J. O'Brien	D6223CIP/A/D/CIP	4713

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EXAMINER
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HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/23/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/919,048

Applicant(s)

O'BRIEN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment and Arguments***

1. Claims 1-18, 22 and 24-31 are pending.

Claims 1-17 and 24-31, drawn to non-elected inventions are withdrawn from examination.

Claims 20, 21 and 23 have been cancelled.

Claims 18 and 22 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application, 60/041,404 (filed 19 March 1997) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 18 and 22 of this application. This provisional application fails to disclose SEQ ID NO: 28 and 148 nor a method of producing activated T cells directed toward hepsin. Accordingly, the examined claims are afforded the priority date of February 22, 2000, the effective filing date of parent application 09/510,738, now U.S. Patent number 6,268,165.

### ***Specification***

4. The first line of the specification should be amended to reflect that U.S. application 09/861,966 is now U.S. Patent number 6,518,028.

***Withdrawn Rejection***

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 18 and 22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn. Claims 20, 21 and 23 have been cancelled.

***Maintained and New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

6. The rejection of claims 18 and 22 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. Claims 20, 21 and 23 have been cancelled. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

“Applicant[s] submit that in view of the results in Example 17 and Figures 20 [and] 21 [and] the well-know fact that dendritic cells are potent antigen presenting cells in vitro and in vivo, one of ordinary skill in the art would predict with reasonable expectation of success that...” the claimed invention is plausible. Applicants also have amended claims in order for them to be commensurate with the scope of enablement provided in the specification. All of these points of view have been carefully reviewed and considered, but found to be partially persuasive.

The Examiner concurs with Applicants in respect to the enabling results of Example 17 found on pages 74-78 and Figures 20 and 21 and the applicability of SEQ

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ID NO: 28 and SEQ ID NO: 148 in producing activated T cells. However as the claims read they embrace an entire hepsin protein and a single amino acid, as set forth by the term "fragment". The disclosure does not support the use of the hepsin protein in its entirety, or the use of less than the peptide consisting of the 9 residues of SEQ ID NO: 28 and SEQ ID NO: 148. Furthermore, it is highly unlikely that the single amino acid residue can generate an immune response. There continues to be insufficient evidence establishing how one of ordinary skill in the art would select particular fragments of hepsin and SEQ ID NO: 28 and 148. There is no disclosure supporting that arbitrary fragments of any length are capable of acting in the manner in which the method requires, for instance to activate immune cells. Likewise, it follows that undue experimentation would be required to make and use the produced activated dendritic cells of the broadly claimed invention. Limited evidence has been provided which would allow one of skill in the art to predict the efficacy of the dendritic cells to confer protective immunity or generate an immune response in any and all cancers with a reasonable expectation of success based on the analysis set forth. In view of the above, one of skill in the art would be forced into undue experimentation to practice implementation of the claimed invention.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paglia et al. (J. Exp. Med. 183: 317-322, January 1996), in view of U.S. Patent number 6,232,456 (filed October 6, 1997). Paglia teaches the priming of an immune response against a major histocompatibility complex class I-restricted antigen by utilizing dendritic cells (DC) for presentation of tumor-associated antigens (TAA), see summary. Paglia continues to teach mice vaccinated with loaded soluble antigen and the subsequent CTL activation. Paglia does not teach a method of producing activated T cell directed toward hepsin comprising the steps of exposing dendritic cells, which have been isolated from an individual prior to exposure to a hepsin protein or fragment of SEQ ID NO: 28 or 148 and subsequent reintroducing dendritic cells.

However, Patent #6,232,456 teaches a serine protease fragment, the same as hepsin fragments, SEQ ID NO: 28 and 148, see attached sequence alignment. These amino acid residues are targets for the design and use of therapeutic treatments for prostate disease and prostate cancer, see column 7, lines 45-50. It would have been *prima facie* obvious at the time of the claimed invention to prime an effective candidate, such as a DC for presentation of the disclosed TAA. One of ordinary skill in the art would have been motivated by the teachings in both documents that "[DC] can be engineered to present any TAA because they are particularly effective in stimulating both CD4 and CD8 naïve T lymphocytes", as well as "...generate T cell-mediated tumor-specific immunity...", see page 317. Furthermore, the disclosed serine proteases

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are known to be involved in proteolytic processes, which are thought to be the critical point in tumor invasion and metastasis, see patent, column 2, lines 43-52.

### ***Double Patenting***

9. Claims 18 and 22 of this application conflict with claims 14-23 of Application No. 10/102,283 (filed March 20, 2003) 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 8 and 22 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-23 of copending Application No. 10/102,283 (filed March 20, 2002). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims from both applications read on a method of producing immune-activated T cells directed toward hepsin, comprising exposing immune cells to a hepsin protein or fragment thereof, which may be from SEQ ID NO: 28 or SEQ ID NO: 148 and reintroducing the activated dendritic cells into an individual subsequent to exposure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4315.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

**ALANA M. HARRIS, PH.D.**

**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.

22 December 2003